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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,414	07/30/2003	Zheng Z. Wu	54334US019	9005

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EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
09/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/630,414	WU ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments, Remarks and IDS filed on 07/05/07. Claims 29 and 37 have been amended. No claims have been cancelled or newly added. Accordingly, claims **29-37** remain pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 29 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Blondino et al (6,290,930).

Blondino et al discloses a **stabilized medicinal aerosol solution** formulations adapted for use in a pressurized aerosol container. The aerosol formulation is formulated from a composition containing **budesonide**, at least one fluoroalkane propellant and a co-solvent (see abstract). It is disclosed that the solution aerosol compositions are filled in a plastic coated glass bottle or an aluminum canister (see col. 4, lines 15-27). The preferred propellants include HFA 134 and HFA 227 or a mixture thereof (col. 3, lines 12-24).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 30 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blondino et al (6,290,930) in view of Ercoli et al (3,755,302).

Blondino et al, discussed above, lacks specific disclosure on other suitable 20-ketosteroid drugs other than budesonide.

Ercoli et al teach process for the production of 17-monoesters of 17α, 21-dihydroxy-20-ketosteroids (see abstract). Such ketosteroids include dexamethasone and betamethasone (see Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the solution formulations of Blondino et al to have looked in the art for other suitable steroids because preparing more stable solution formulations for aerosol delivery with other active agents would provide patients and health care providers with more options and better therapeutic outcomes. In other words, the claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Saidi et al (6,241,969).

Ashurst et al teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation (see abstract). Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid such as fluticasone, beclomethasone, **budesonide, triamcinolone acetonide**, etc (see col. 3, lines 15-30).

Ashurst's compositions contain propellants and suitable propellants include HFA 134a and HFA 227 (see col. 3, lines 55-67). The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or **plastic**. The internal surface of the inhaler can be **coated** by a fluorocarbon polymer (see col. 4, line 47 to col. 5, line 25). It is also disclosed that MDI cans may be coated by the means known in the art of metal coating such as spray-coating (see paragraph bridging col. 5 and col. 6). Ashurst et al's formulations are in suspension form and lacks specific disclosure on solutions.

Saidi et al teach compositions containing corticosteroids in a dissolved state in the composition. The said corticoteroids include betamethasone, budesonide, triamcinolone, dexamethasone, dexamethasone 21-isonicotinate (see abstract and col. 6, lines 8-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Ashurst et al on formulations containing active agents such as corticosteroids for inhalation stored in and delivered by a meterd dose inhaler having a non-metal interior to have looked in the art for other dosage forms of the formulation such as solutions as taught by Saidi et al with the reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Saidi et al (6,241,969) as applied to claims 29-31 above and further in view of Wiliams et al, European journal of pharmaceutics and biopharmaceutics 44 (1997) 195-203.

The combination of Ashurst et al and Saidi et al, discussed above, lacks specific disclosure on the specifics of coatings as claimed in claims 34-37.

Williams et al disclose a study of an epoxy aerosol can lining exposed to hydrofluoroalkane propellants. It is disclosed that the pressurized MDIs consist of a

canister containing active drug, a valve and an actuator. The drug is formulated in the canister as a suspension or solution dispersed in a propellant, typically HFAs. The stability of the formulation and the accuracy of the emitted dose are influenced by formulation composition and the choice of the material composition of the delivery device. Various materials such as glass, aluminum and tin plates are used to manufacture pMDIs. Generally, the internal surface of the container is lined with an inert organic coating (see pages 195-196).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the references because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **29-37** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-37 of copending Application No. 11/061,529 (US 20050220717). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Specifically, the reference claims are drawn to a medicinal aerosol solution metered dose inhaler product comprising a 20-ketosteroid drug and one or two HFA propellants in a container that has an anon-metal interior surface. The instant claims are drawn to a pressurized metered dose inhaler containing a solution of an active agent (such as a 20-ketosteroid) an HFA propellant, having part or all of its internal surface consisting of a stainless steel, aluminum or coated with an inert coating. Although the instant claims are of a slightly broader scope, they are obvious over the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments, filed 07/05/07, with respect to the rejection(s) of claim(s) 29-37 under 35 USC 120(e) over Lewis et al have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made (see above).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 07/05/07 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
September 13, 2007

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600